

WY P&T Committee Meeting Minutes
Thursday, November 12, 2020
Cheyenne, WY via Zoom
10 a.m – 1 p.m.

Members present: Melinda Carroll, Hoo Fang Choo, Joseph Horam, Paul Johnson, Scott Johnston, Kristen Lovas, Robert Monger, Chris Mosier, Garry Needham, Scot Schmidt

Excused: Alissa Aylward, Patrick Yost

Ex-officio: Cori Cooper, Melissa Hunter, James Bush

Guests: Melissa Eames, Sandra Deaver, Amy Stockton (CHC), Matt Robison (CHC), Nikki Yost (CHC), Aimee Weems (Acorda), Anne Stratton (Children's Hospital Colorado), Jane Stephen (Amgen), Jason Smith (Gilead), Jenna Gianninoto (Abbvie), Kim Walter (Janssen), Leslie Zanetti (Sarepta), Mike Donabedian (Sarepta), Roy Lindfield (Sunovion), Joe Ferroli (Takeda), Chi Kohloff (Viel Bio), Mary Stoots (Artia Solutions), Hiten Patadia (OTSUKA), Ben Volpe (Genetech), Aimee Redhair (Biogen), Mary Jenkins (Abbvie), Roy Lindfield (Sunovian) Amy Rodenburg (Abbvie), Melissa Sommers (Novartis), Jody Legg (Alkermes), David Testerman (CHC), Susan Kelly (Spark Therapeutics), Michael Faithe (Amgen), Jeremy Strand (Alexion), Jill Adams (Genetech), Britt Boehner (Lilly USA, Inc), David Large (Biohaven Pharmaceuticals), Bryan Yeager (Genetech), Tami Sova (Biogen), Michele Puyear (Genetech), Suzanne Morgan (NS Pharma), Kelly Maynard (Little Hercules Foundation), Rachel Williams (Amgen), Ashley Johnson (OTSUKA), Britt Ward (Genetech), Matt Bradley (Novartis), Bill Eicholzer (Alexion)

Dr. Monger called the meeting to order at 10:00 a.m.

Introductions were made.

Approval of Minutes

The minutes of the August 13, 2020 meeting were approved.

Department of Health

A. Pharmacy Program Manager Report: Donna Artery retired in October. They will be rehiring that position. The Department continues to work towards integrating pharmacy data with other Medicaid data systems. The budget cuts continue. Select staff have furlough days scheduled through January, however, that will likely be extended in to the spring of 2021. They are working remotely as much as possible and have access to their offices as needed.

B. Medical Director Report: Dr. Bush is working with the Medicaid Medical Directors, heading up a task force on high cost and fast tracked medications. They will be reaching out to the other Medicaid leadership groups and the National Governor's Association. Drug costs are not sustainable, particularly with state budget cuts. They hope to have a white paper complete by the end of January.

Scot mentioned that he was on a call regarding high cost drugs. Requiring these medications to be delivered via mail order or specialty pharmacies has driven the cost up 10-fold over using community pharmacies.

Dr. Horam provided perspective from third party payers, indicating that they are also very concerned and believe there should be collaborative action. Currently, PhRMA is controlling the market with no competition or price negotiation. Dirt cheap, older drugs are seeing large price increases and fast track drugs are being approved with no data or minimal proven clinical effects.

C. DUR Manager Report: None

Old Business:

A. Vyondys 53 was brought back for additional discussion. Sarepta pharmaceuticals provided additional information as requested. Leslie Zanetti (Sarepta) provided public comment. Clinical effects including walk test, loss of ambulation and FVC were investigated, with numerical improvement, but no statistically significant difference. Dr. Horam asked if there was any evidence of improved response based on age of onset, and if there is any basis to provide the medication to teens. The study population is 6 – 15 years of age. Scientifically, you would see benefit, but it would be up to the clinician to make that decision. Dr. Johnston noted that with the approval of Viltepso, there are two medications approved to treat the same gene mutation. Will people want to use both? As they have the same mechanism of action, there is no reason to use both.

Dr. Stratton provided public comment. Dr. Monger asked at what age do we start treatment. Newborn screening does not exist yet, however, many patients present at age 4 or 5. It makes sense to treat as soon as these children present with symptoms, or earlier with a strong family history. Dr. Stratton does not have a strong opinion regarding the difference between Viltepso and Vyondys. They continue to gain experience with both drugs. Dr. Horam noted that these new medications provide some benefit. An ultimate benefit in longevity has not yet been proven. Dr. Bush asked for insight into treating older patients. Dr. Stratton advocates for older patients to have the opportunity for treatment if they have preserved upper extremity function. Chris asked about the truncated vs. normal dystrophin production. Dr. Stratton indicated that the truncated dystrophin that is produced by those with less severe forms (Becker's) makes a very significant difference over no dystrophin. Melissa asked when treatment should be discontinued. It is a role of diminishing returns at some point. Dr. Stratton evaluates patients every six months. They want to see an 18-month trend of declining function before making a decision.

Kelly Maynard, a Duchenne's parent and patient advocate was on the call and available for any questions.

The Committee discussed limiting to Specialists. Given our remote nature, we have not required this for other drugs. Would it be possible to use telehealth between the local

prescriber and the specialists? Dr. Stratton explained that the first two infusions occur in the hospital and then transition to home-based infusion. If resources are available, they would be able to complete the home-based infusions in their community. Dr. Johnson noted that our patients who have Duchenne's are already seeing a specialist. This is true of those with complicated diagnoses in general.

Dr. Choo asked about adherence to the medication. Dr. Stratton's clinic has only dosed one patient commercially, so she is unable to comment. Kelly Maynard commented that any issues with adherence are not for a lack of trying on the part of the patient and their family. It is generally related to available resources in their community.

There was a motion to allow Vyondys 53 for patients with Duchenne's muscular dystrophy that is amenable to exon 53 skipping. Patients will be required to have oversight by a pediatric neurologist and/or a rehabilitation specialist. Prior authorizations will be review on an annual basis, specifically looking at ventilation requirements, the Brooks Upper Limb scale (6 or less), and the NSAA (overall drop greater than 5) for ambulatory patients. There was a second and all were in favor of these criteria. In addition, patients will be referred to the Pharmacy Case Management program.

Viltepso was discussed while on the Duchenne's topic. Dr. Stratton told the Committee that she is very excited about this new medication and would duplicate the thoughts in her letter for this drug. She is still gaining experience to know about preference between the two. There is currently no comparative data; however, there is a small amount of clinical data published for Viltepso, which may push towards that drug a bit. The data is in small numbers and a relatively short period of time. The data is very encouraging.

The Committee noted that there is no evidence of a difference in safety or efficacy between the two drugs. There was a motion to apply the same criteria as Vyondys. There was a second and all were in favor.

B. Prevalence of Parkinson's in Wyoming Medicaid based on diagnosis claims was reviewed. It would appear that much of the drug utilization is in psychiatry.

C. The incidence of Dravet syndrome was reviewed. Because the ICD-10 code specific to Dravet became active on October 1; there is no Medicaid data to review. Karen with Greenwich Biosciences gave an estimate based on national data.

New Business

A. PA Criteria

1. Review existing criteria

i. CGRP agent use in pediatrics was discussed. Dr. Johnson believes we should allow in children. He sees many patients with chronic sinusitis with migraine. They do well with treatment. Dr. Horam mentioned that the acute agents are not all the best physiologically for adolescents and they are not very compliant. There

was a motion to allow for patients 15 years old and older with the same criteria applied to adults. There was a second and all were in favor.

ii. Based on new data for Farxiga in heart failure, it was recommended that a trial and failure of Farxiga be required prior to use of Entresto. This is likely a class effect and the issue will be brought back if other SGLT2 inhibitors publish similar data. There was a motion and a second to require a 90-day trial of Farxiga in the previous 12 months prior to use of Entresto.

Dr. Monger asked Dr. Johnston if he had information regarding the antibiotic data he has been reviewing. Dr. Johnston will have it at a later date. He is looking at specific CDC criteria regarding drug of choice, mostly in upper respiratory infections. At this time, he can tell us that antibiotics are prescribed for viral infections 48% of the time in Wyoming, vs. the national average of 37%.

2. New Drugs

i. Bafiertam is approved for treatment of relapsing forms of multiple sclerosis in adults. It was approved based on bioavailability studies compared to dimethyl fumarate. The Committee found no evidence of a difference in safety or efficacy and referred it to the Department of Health for cost analysis.

ii. Evrysdi is approved for treatment of spinal muscular atrophy in patients aged 2 years and older. Michele Puyear (Genentech) provided public comment. Wyoming does have newborn screening for SMA now. This is approved for patients with type 1 and type 2 SMA. It is the first orally administered medication. It can be given by a g-tube; however, most patients in the study had the ability to swallow. Dr. Horam pointed out that some may require a g-tube and other life-preserving intervention, as they will exceed their expected life span. The real value will be for infants with type 1. Type 3 will be interesting to watch. Will the SMA agents be used in combination? This medication would be expected to replace Spinraza. There is a study that looked at this medication in patients who had received the other two drugs. However, there was a significant washout period and the medications were not used concurrently. Chris noted that there may be a safety advantage over Spinraza based on the route of administration. There was motion and second to limit to indication. There is no comparative evidence. A hard PA should be in place for combination therapy. It was noted that integration with other systems would be necessary to identify concurrent therapy. All were in favor.

iii. Enspryng is indicated for the treatment of neuromyelitis optica spectrum disorder. Michele Puyear (Genentech) provided public comment. This is a rare disease, about 15,000 patients in the US. It is often confused with MS. There is a new test that helps to distinguish it now. This is the only IL-6 inhibitor that can be injected at home. There was a motion, second and all were in favor of limiting to indication.

iv. Kesimpta is approved for the treatment of relapsing forms of multiple sclerosis. Melissa Sommers (Novartis) provided public comment. It is a fully human CD-20 molecule. It is the first to be self-administered. It had a significant impact on relapse rates and is well tolerated. Dr. Horam mentioned that there are so many products in this category; there is really something for everyone. What makes this stand out? Michele noted the high efficacy, positive safety profile and self-administration. There is comparative data against only one medication of many. The Committee agreed

that there is not sufficient evidence of a difference in safety or efficacy with the class as a whole. Kesimpta will be referred to the Department of Health for cost analysis.

v. Ongentys is approved for treatment of patients with Parkinson's experiencing "off" episodes as adjunct therapy with levodopa/carbidopa. There was a motion to limit to indication. A larger class review may be necessary in February based on the prevalence and utilization data provided earlier.

vi. Conjupri is the active isomer (levamlodipine) of amlodipine. It is indicated for treatment of hypertension. There is no evidence of a difference in safety and efficacy and Conjupri will be referred for cost analysis. All were in favor.

3. Determine need for criteria

i. Guanfacine dosing was reviewed due to high doses identified in claims analysis. There is no pattern in prescribers. The risk for drug-drug interactions with guanfacine was also noted. Doses will be limited to labeled maximum and requests for higher doses will be sent to Seattle Children's Hospital for second opinion.

4. Other

i. A correction letter regarding Veposia was submitted following the August meeting. The correction is as follows:

In the second paragraph of question 4, in the written summary, the last 2 sentences incorrectly stated that "Furthermore, ozanimod is the only S1P modulator that does not require genetic testing prior to initiation. Ozanimod also does not require ophthalmic testing for most patients." These sentences should have read, "Furthermore, ozanimod does not require genetic testing prior to initiation, nor ophthalmic testing for most patients.1 "

ii. The draft 2021 Preferred Drug List was reviewed. Comments should be sent to Aimee or Cori prior to December 4, 2020.

iii. Written public comment was submitted requesting the availability of Abilify Maintena as a preferred agent. The draft 2021 PDL does list Abilify Maintena as preferred. Aimee will follow up with the providers who submitted comment.

There being no further business, the open portion of the meeting adjourned at 12:39 pm and the Committee met in closed session.

Respectfully Submitted,

Aimee Lewis
WYDUR Manager